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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,433	02/16/2006	Michael Goldberg	817.1013US	9801

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PEARL COHEN ZEDEK LATZER, LLP
1500 BROADWAY 12TH FLOOR
NEW YORK, NY 10036

EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,433	GOLDBERG ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24,25,27-29,33-38 and 40-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24,25,27-29,33-38 and 40-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the directives of the response filed 6/19/07, claims 1, 12-14, 16, 22, 24, 25, 27, 34 have been amended, and claims 40-67 added. Claims 1-22, 24, 25, 27-29, 33-38, 40-67 remain pending.

. . . .

In view of the claim limitations, claims 2-4, 29 and 35 are now rejoined with the elected claims. Claims 1-22, 24, 25, 27-29, 33-38, 40-67 are examined in this Office action.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 29 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 recites "preventing" *beta* cell death, claim 3 recites "protection" from diabetes, and claim 29 recites "prophylactically sparing" *beta* cell function. The term "preventing" (in reference to *beta* cells) means that if the insulin is administered, not a single *beta* cell will die. Perhaps it is true that the

incidence of cell death will decrease if insulin is administered (before bedtime, or at some other time). But a reduction of the incidence is not the same as completely eliminating all cell death. Applicants limited data does not even begin to show that cell death can be completely eliminated. Similarly, the term "protection" (in reference to diabetes) would imply that prevention can be achieved. If insulin were administered to each of 10,000 subjects exhibiting impaired glucose tolerance, and 9,999 of them never developed symptoms of diabetes, the fact that one such subject had developed the disease would demonstrate that prevention had not been achieved. Applicants have made no attempt to demonstrate outright prevention.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required to practice the claimed invention.

✦

Claims 1-22, 24, 27-29, 33, 35-38, 47, 48, 66, 67 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite that the delivery agent "comprises" 4-CNAB. Certainly, there are several references to CNAB in the specification. However, what is described is an agent which **is** 4-CNAB, not an agent that "comprises" CNAB. There may also be descriptive support for a pharmaceutical composition that comprises insulin and CNAB, but again, there is no support for a delivery agent "comprises" 4-CNAB. [It is noted that claim 33 as filed did recite the term "comprises" in reference to CNAB. However, the invention referred to in that claim is different from the invention of instant claim 1].

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 25, 34, 40-46, 49, 50-65 are rejected under 35 U.S.C. §103 as being unpatentable over Pilarski (USP 7,137,951) in view of Byrd (USP 7,118,762) or Moye Sherman (USP 7,115,663) or Ekwuribe (USP 7,084,114) or Ekwuribe (USP 7,060,675).

Pilarski discloses (col 30, line 59) administration of insulin at bedtime. Pilarski does not specify oral administration. Each of the secondary references discloses orally administrable forms of insulin.

Thus, it would have been obvious to use one of the orally administrable forms of insulin for the advantages cited therein.

With regard to the issue of priority to the provisional applications, applicants have argued that the term "bedtime" can be found somewhere in the claims of the provisional applications. Applicants are correct that the term "bedtime" can be found somewhere in the claims of the provisional applications, but this does not mean that the invention which is presently claimed is described by those claims which recite the term "bedtime". As it happens, the inventions which are described by those claims in the provisional applications which recite the term "bedtime" are different from those presently claimed.

✧

Claims 25, 34, 40-46, 49, 50-65 are rejected under 35 U.S.C. §103 as being unpatentable over Ekwuribe (USP 7060675).

Ekwuribe discloses (e.g., col 4, line 10; col 4, line 45) orally administrable insulin. Also disclosed (col 11, line 65) is administration at bedtime.

Thus, the claims are rendered obvious.

✧

Claims 25, 34, 40-46, 49, 50-65 are rejected under 35 U.S.C. §103 as being unpatentable over Miller J. L. (*Clinical Pharmacology and Therapeutics* 53(3), 380-4, 1993) in view of (a) Mesiha Mounir S. (*International Journal of Pharmaceutics* 249(1-2), 1-5, 2002) or (b) Hosny Ehab A. (*International Journal of Pharmaceutics* 237(1-2), 71-6, 2002) or (c) Clement Stephen (*Diabetes Technology & Therapeutics* 4(4), 459-66, 2002).

Miller discloses that administering insulin at bedtime is beneficial. Miller does not disclose oral administration of insulin. However, each of the secondary references discloses orally administrable insulin, and the benefits associated therewith.

Accordingly, it would have been obvious to one of ordinary skill to use orally administrable insulin at bedtime.

✧

Claims 25, 34, 40-46, 49, 50-65 are rejected under 35 U.S.C. §103 as being unpatentable over Yki-Jarvinen H. (*Annals of internal medicine* 130(5), 389-96, 1999) in view of (a) Mesiha Mounir S. (*International Journal of Pharmaceutics* 249(1-2), 1-5, 2002) or (b) Hosny Ehab A. (*International Journal of Pharmaceutics* 237(1-2), 71-6, 2002) or (c) Clement Stephen (*Diabetes Technology & Therapeutics* 4(4), 459-66, 2002).

Yki-Jarvinen discloses that administering insulin at bedtime is beneficial. Yki-Jarvinen does not disclose oral administration of insulin. However, each of the secondary references discloses orally administrable insulin, and the benefits associated therewith.

Accordingly, it would have been obvious to one of ordinary skill to use orally administrable insulin at bedtime.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER